Afternoon Session

Of Acceptable Risk (Lowrance)

Organization of this book The natur safety decisions Measuring Risk Sou of evidence The four lines of investiga Defining the conditions of exposure the adverse effects Relating exposur effect Estimating overall risk Of the evidence Experimen on human subjects Acceptable inadvertent and o exposure Mal Risk epidemiologica Experimenting SCIENCE AND THE nonhuman org DETERMINATION Testing product Problems of in **OF SAFETY** Relating cause effect Is the differe William W. Lowrance significant? Extrapola from animals to man Sor out synergistic and antagonistic eff Evaluating chronic, low-level agents risk Judging Safety Guides to accept Empirical criteria of acceptability array of considerations Decisions, de decisions Safety Issues as Public Prob From guiet to crisis, and back Who Matters of fact, matter the arena? value In the public interest In the co In the media On being, and being h responsible Making Safe Making safe regulation Criteria and standards Ma products safe Making the general en safe Making the workplace safe Ma safe through education Monitoring surveillance Paying for it DDT: An A

William Lowrance 1977

"A thing is safe if its risks are judged to be acceptable." **Therefore** We need to have sufficiently certain estimates of risk And, we need to have a judgment on acceptability of risk.

What health effects are of concern?

- To the public generally
- To policy-makers
- To parents
- To other groups

What Is An "Adverse Effect"

1985 statement of the American Thoracic Society

"Guidelines as to what constitutes an adverse respiratory health effect, with special reference to epidemiological studies of air pollution"

Medically significant physiologic or pathologic changes generally evidenced by one or more of the following:

- Interference with the normal activity of the affected person or persons
- Episodic respiratory illness
- Incapacitating illness
- Permanent respiratory injury and/or
- Progressive respiratory dysfunction

What Is An "Adverse Effect"

2000 statement of the American Thoracic Society

"What Constitutes an Adverse Health Effect of Air Pollution?"

- A. Increased mortality
- B. Increased incidence of cancer
- C. Increased frequency of symptomatic asthmatic attacks
- D. Increased incidence of lower respiratory tract infections
- E. Increased exacerbations of disease in persons with chronic cardiopulmonary or other disease that could be reflected in a variety of ways
 - 1. Less able to cope with daily activities (i.e., shortness of breath or increased anginal episodes)
 - 2. Increased hospitalization, both frequency and duration
 - 3. Increased emergency ward or physician visits
 - 4. Increased pulmonary medication
 - 5. Decreased pulmonary function
- F. Reduction in FEV1 or FVC associated with clinical

symptoms

- 1. Chronic reduction in FEV1 or FVC associated with clinical symptoms
- A significant increase in number of persons with FEV1 below normal limits: chronically reduced FEV1 is a predictor of increased risk of mortality.
- 3. An increased rate of decline in pulmonary function (FEV1) relative to the predicted value in adults with increasing age or failure of children to maintain their predicted FEV1 growth curve.

- G. Increased prevalence of wheezing in the chest apart from colds, or of wheezing most days or nights.
- H. Increased prevalence or incidence of chest tightness
- Increased prevalence or incidence of cough/phlegm production requiring medical attention
- J. Increased incidence of acute upper respiratory infections that interfere with normal activity
- K. Acute upper respiratory tract infections that do not interfere with normal activity
- L. Eye, nose, and throat irritation that may interfere with normal activity (i.e., driving a car) if severe
- M. Odors

What Is An "Adverse Effect"

2017 statement of the American Thoracic Society

"A joint ERS/ATS policy statement: what constitutes an adverse health effect of air pollution? An analytical framework"

TABLE 1 Considerations for assessing adversity of clinical or pathological effects

Consideration	Pertinent questions
1. Fatality	Does air pollution exposure lead to an increase of short-term or long-term mortality?
2. Persistence of effect	How persistent over time is the effect? (Generally, chronic effects such as the induction of new disease are given greater weight, although short-term exposures may lead to changes that increase risk for triggering acute adverse events, such as myocardial infarction)
3. Population risk	Is there a shift in the population risk distribution of an adverse event?
4. Susceptibility	Are the very young, older adults or individuals with pre-existing health conditions or specific genetic characteristics more likely to be affected?
5. Medical/functional significance	Is there evidence of one or more of the following? 1) severe interference with a normal activity of the affected person or persons; 2) incapacitating illness; 3) permanent injury; 4) progressive dysfunction; 5) reduced quality of life

Adverse Effects



Emerging Risks



Emerging Risks

- Reproductive outcomes
 - Birth weight
 - Neuropsychological development
 - Neuropsychological disorders (autism)
- "Brain aging"
 - Increased cognitive decline
 - Alzheimer's Disease
- Welfare effects
 - Mood
 - Suicide risk

Explaining and using the findings

Technical details

- Exposure measures
- Measures used—HRs and ORs
- Dose-response functions
- Uncertainty
- What is adverse
- Disease burden estimates
- Causation (or not)



▲ Dr Tedros Adhanom Ghebreyesus speaks at a press conference in 2017. Photograph: Fabrice Coffrini/AFP/Getty Images

Air pollution is the "new tobacco", the head of the World Health Organization has warned, saying the simple act of breathing is killing 7 million people a year and harming billions more.

The Clean Air Act





Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, is requisite to protect the public health."

NAAQS= National Ambient Air Quality Standard

The NAAQS: From Evidence to Standards

